II. Remarks

A. Status of the Claims

Claims 1-18, 24, 29-41, and 54 have been amended without prejudice. Support for the amendments can be found throughout the specification and in the original claims.

New claims 62 to 64 have been added. Support for new claim 62 can be found, e.g., on page 10, lines 16-17, of the specification as filed. Support for new claims 63 and 64 can be found, e.g., on page 66, lines 20-23, of the specification as filed.

Claim 60 has been previously cancelled without prejudice.

Claims 1-59 and 61-64 are pending.

Applicants respectfully submit that no new matter has been added by virtue of the present amendments.

B. Substance of Interview

In accordance with the provisions of 37 CFR 1.133, Applicants herein make of record the substance of the interview conducted on July 22, 2008, between Applicants' attorneys, Philip C. Strassburger and Oleg Ioselevich, and Examiners Humera N. Sheikh and James-Henry Alstrum-Acevedo.

During the interview, the following references were discussed in view of the present claims and the rejections made in the Office Action of April 4, 2008: WO 99/32120 to Palermo; U.S. Patent No. 4,844,907 to Elger et al. and U.S. Patent No. 5,149,538 to Granger et al.

Applicants thank the Examiners for granting the interview, and respectfully request that the substance of interview be made of record.

C. Claim Rejections 35 U.S.C. § 103

Claims 1-59 and 61 were rejected under 35 U.S.C. § 103(a) over WO 99/32120 to Palermo ("the Palermo publication").

Independent claims 1, 2, 3, 4, 5, 7, 8, 9, and 54 have been amended without prejudice to recite that "a sequestering material separate[s] the antagonist from the agonist ..."

Independent claims 6 and 41 have been amended without prejudice to recite in part "a sequestering material separating naltrexone from the agonist."

The Palermo publication describes dosage forms in which an opioid antagonist and an opioid agonist are combined in such a way that "at least a two-step extraction process" would be required to separate the opioid antagonist from the opioid agonist. See, e.g., Abstract; page 6, lines 12-14.

The Palermo publication does not teach or suggest an opioid agonist separated from the opioid antagonist as recited in the amended independent claims. In fact, it is respectfully submitted that such modification would frustrate the purpose of the Palermo publication.

With further regard to claim 5, it is respectfully submitted that the Palermo publication does not teach a degree of sequestration "such that an amount of the antagonist released from the intact dosage form after 1 hour is less than an amount bioequivalent to 0.25 mg naltrexone and amount of the antagonist released after 1 hour from the dosage form after tampering is an amount bioequivalent to 0.25 mg naltrexone or more."

With further regard to claims 1, 2, 3, and 4, it is respectfully submitted that the Palermo publication does not teach or suggest a degree of sequestration "such that a ratio of an amount of the antagonist released from the dosage form after tampering to an amount of the antagonist released from the intact dosage form is about 4:1 or greater" as recited in claims 1 to 3; and "such that a ratio of an amount of the antagonist contained in the intact dosage form to an amount of the antagonist released from the intact dosage form after 1 hour is about 4:1 or greater" as recited in claim 4.

With further regard to claim 6, it is respectfully submitted that the Palermo publication further does not teach or suggest a degree of sequestration "such that an amount of the naltrexone released from the intact dosage form after 1 hour is less than 0.25 mg and an amount of the naltrexone released after 1 hour from the dosage form after tampering is 0.25 mg or more."

With further regard to claim 7, it is respectfully submitted that the Palermo publication does not teach or suggest a degree of sequestration "such that at 1 hour after oral administration, the dosage form releases not more than 25% of the antagonist."

For the foregoing reasons, Applicants submit that the Palermo publication does not render the present claims obvious and respectfully request withdrawal of the rejection.

III. Conclusion

An early and favorable action on the merits is earnestly solicited. According to currently recommended Patent Office policy the Examiner is requested to contact the undersigned in the event that a telephonic interview will advance the prosecution of this application.

Respectfully submitted,
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